

**Notice of Allowability**

Application No.

09/487,851

Examiner

Q. Janice Li

Applicant(s)

LEVY ET AL.

Art Unit

1632

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to 2/23/04.
2. ☒ The allowed claim(s) is/are 4,5,16,17,31-33,36-38,65,67 and 68.
3. ☒ The drawings filed on 21 December 2000 are accepted by the Examiner.
4. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
  - a) ☐ All b) ☐ Some\* c) ☐ None of the:
    1. ☐ Certified copies of the priority documents have been received.
    2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
    3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\* Certified copies not received: \_\_\_\_\_.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.

**THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.**

5. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
  6. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
    - (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
      - 1) ☐ hereto or 2) ☐ to Paper No./Mail Date \_\_\_\_\_.
    - (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date \_\_\_\_\_.
- Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
7. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

**Attachment(s)**

1. ☒ Notice of References Cited (PTO-892)
2. ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3. ☐ Information Disclosure Statements (PTO-1449 or PTO/SB/08), Paper No./Mail Date \_\_\_\_\_
4. ☐ Examiner's Comment Regarding Requirement for Deposit of Biological Material
5. ☐ Notice of Informal Patent Application (PTO-152)
6. ☒ Interview Summary (PTO-413), Paper No./Mail Date \_\_\_\_\_
7. ☒ Examiner's Amendment/Comment
8. ☒ Examiner's Statement of Reasons for Allowance
9. ☐ Other \_\_\_\_\_.

### **DETAILED ACTION**

This action is in response to Amendment filed February 23, 2004. Claims 34 and 39 have been cancelled. Claim 4 has been amended. Claims 4, 5, 16, 17, 31-33, 36-38, 65, 67, 68 are pending in the application and under current examination. The amendment and response have been thoroughly reviewed and entered. The previous rejections in the Office action of 11/20/03 are withdrawn in view of the amendment and the following Examiner's amendment.

### ***EXAMINER'S AMENDMENT***

An extension of time under 37 CFR 1.136(a) is required in order to make an examiner's amendment that places this application in condition for allowance. During a telephone conversation conducted on 3/17/04, the Applicant's representative Kathleen D. Rigaut requested an extension of time for one MONTH(S) and authorized the Commissioner to charge Deposit Account No. 04-1406 the required fee of \$55.00 for this extension and authorized the following examiner's amendment. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it **MUST** be submitted no later than the payment of the issue fee.

The claims have been amended as follows:

Claim 4. (currently amended) A method of alleviating re-entrant ~~reentry~~ atrial flutter in an affected animal ~~cell~~, said method comprising locally delivering to a cardiac cells of the animal a plasmid reverse gene therapy vector comprising a promoter operably linked with a nucleic acid encoding ~~a therapeutic gene product which is usually only expressed in cells of an abnormal tissue that is not afflicted with reentry atrial flutter, wherein said therapeutic gene product is a defective~~ human ether agogo gene (HERG) protein, and whereby delivery of said vector to the affected cardiac cells alleviates the flutter.

In claim 16, --tissue-specific-- was inserted in place of "tissue specific" in line 2.

Claim 31 (currently amended) The method of claim 4, wherein the cardiac cells are is a myocardial cells.

Claim 32 (currently amended) The method of claim 31, wherein the cardiac cells are is a right atrial myocardial cells.

Claim 33 (currently amended) The method of claim 31, wherein the cardiac cells are is a cells of the crista terminalis.

In claim 67, --a-- was inserted before "cardiac" in line 2.

The following is an examiner's statement of reasons for allowance:

Claims 4, 5, 16, 17, 31-33, 36-38, 65, 67, 68 are drawn to a method of alleviating re-entrant atrial flutter in an affected animal, the method comprises directly administering a plasmid vector encoding a defective HERG protein to cardiac cells of the affected animal. Although various defective HERG proteins and their association with a heart disease, particularly the Long QT syndrome, are well known in the art, such as those cited in the specification (e.g. pages 11-14), and in the US patent 6,207,383, the prior art of record fail to teach or fairly suggest to use the defective HERG protein for treating another type of heart disease, re-entrant atrial flutter. The applicant has shown in the specification and in the subsequently submitted papers (3/5/02 & 11/10/03) that locally delivering a plasmid vector expressing a defective HERG protein indeed affected the electrophysiological status of cardiac cells as desired in cell cultures and animal models.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

### ***Conclusion***

Claims 4, 5, 16, 17, 31-33, 36-38, 65, 67, 68 are allowed.

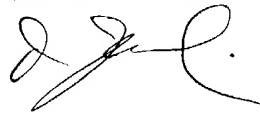
Any inquiry concerning this communication or earlier communications from the examiner should be directed to **Q. Janice Li** whose telephone number is 571-272-0730. The examiner can normally be reached on 9:30 am - 7 p.m., Monday through Friday, except every other Wednesday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, **Amy Nelson** can be reached on 571-272-0804. The fax numbers for the organization where this application or proceeding is assigned are **703-872-9306**.

Any inquiry of formal matters can be directed to the patent analyst, **Dianiece Jacobs**, whose telephone number is (571) 272-0532.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist **Rena Jones** whose telephone number is **571-272-0571**.

JANICE LI  
PATENT EXAMINER



Q. Janice Li  
Patent Examiner  
Art Unit 1632



March 19, 2004